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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/881,556 | 06/14/2001 | J. Neil Simonsen | 9000-0054 | 6837 |

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| EXAMINER |
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NAVARRO, ALBERT MARK

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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 06/04/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/881,556

Applicant(s)
Simonsen

Examiner
Mark Navarro

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) 2, 5, and 9-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1645

DETAILED ACTION

Applicants amendment filed March 31, 2003, (Paper Number 11) has been received and entered. Consequently claims 1-31 remain pending in the instant application, of which claims 2, 5 and 9-31 have been withdrawn from further consideration as being drawn to a non-elected invention in Paper Number 9, received October 15, 2002.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1, 3-4, and 6-8 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. This is a written description rejection.

Applicants are asserting that the nucleic acid molecules of claim 1 code for an “immunogenic” polypeptide, and that the nucleic acid molecules of claim 3 also code for an “immunogenic” polypeptide that has “80% identity” to nucleotide positions 9-587 of SEQ ID NO:

3. Applicants conclude that they have provided a common attribute and characteristic for nucleic acid molecules that fall within the recitation of the claims, namely, that the molecules encode proteins that are immunogenic.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Art Unit: 1645

Applicants assert that the nucleic acid molecules of claim 1 code for an “immunogenic” polypeptide, and that the nucleic acid molecules of claim 3 also code for an “immunogenic” polypeptide that has “80% identity” to nucleotide positions 9-587 of SEQ ID NO: 3. However, Applicants have not described any function of the polypeptide. Any peptide of 5 or greater amino acids under the right conditions will elicit an immune response. Consequently, Applicants claimed function of “immunogenicity” in no way identifies members of a genus, since every single one of the polypeptides is capable of “immunogenicity.” Applicants are again respectfully directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999, which set forth of Examples which describe functions which can adequately describe members of the genus (e.g., hydrolase, ATPase, racemase, etc.).

Claims 1, 3-4 and 6-8 recite an isolated nucleic acid molecule comprising a coding sequence for an immunogenic *C. parvum* polypeptide comprising a *C. parvum* antigenic polypeptide 2 (AG2), or a fragment of said nucleic acid molecule comprising at least 15 nucleotides, and wherein the nucleotide sequence has at least 80% identity to the nucleotide sequence shown at nucleotide positions 9-587, inclusive, of Figure 2A (SEQ ID NO:3).

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants,

Art Unit: 1645

and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 3 encoding SEQ ID NO: 4 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by SEQ ID NO: 3 encoding SEQ ID NO: 4 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. It is further noted that SEQ ID NO: 4 does not appear to be a full length protein, given that the classical start codon, methionine, is absent.. Given that the function of the non-full length protein is not set forth, the written description of the instant application is supportive of only an antigenic peptide consisting of SEQ ID NO: 4 since additional amino acids on the N-terminus or C-terminus will have a profound impact on the activity of the protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Art Unit: 1645

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record in Paper Number 10, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "at least about 80%" and "at least about 15 nucleotides." is maintained.

It is noted that Applicants have amended the claim to recite "at least 80% identity." This phrase is no longer rejected under 112 second. However, Applicants claim still recites "at least about 15 nucleotides."

"At least" one thousand degrees in claim means minimum temperature of one thousand degrees "About" in claim allows some tolerance. National Research Development Corp v. Great Lakes Carbon Corp. (DC Del) 188 USPQ 327. Consequently, the term at least about confers two separate contradictory limitations.

Applicants have not provided any arguments concerning this rejection, accordingly the rejection is maintained for reasons of record in Paper Number 10, mailed December 31, 2002.

Art Unit: 1645

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The rejection of claims 1, 4, and 7-8 under 35 U.S.C. 102(e) as being anticipated by Perryman *et al* is maintained.

Applicants are asserting that the only sequence with significant alignment under BLAST is sequence 3 from PCT publication WO0196370, which is the corresponding PCT application of the pending application. Applicants further assert that the nucleotide sequences of SEQ ID NO: 3 of the pending application were compared to SEQ ID NO: 1 of Perryman *et al*, and no significant homology was observed. Lastly, Applicants assert that the amino acid sequences of SEQ ID NO: 4 of the pending application were compared to SEQ ID NO: 2 of Perryman *et al*, and no significant homology was observed.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be persuasive in view of the disclosure of Perryman *et al*.

Art Unit: 1645

Applicants have obviously put a substantial effort comparing the sequences of the instant application with that of the prior art and Applicants arguments are not disputed. However, Applicants arguments are not germane to the rejection, given that not a single one of the rejected claims recites any SEQ ID NO at all. Consequently, any lack of substantial homology to a particular SEQ ID NO is not relevant to a claim which does not recite a SEQ ID NO in the first place. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The claims are directed to an isolated nucleic acid molecule comprising a coding sequence for an immunogenic *C. parvum* polypeptide comprising a *C. parvum* antigenic polypeptide 2 (AG2), or a fragment of said nucleic acid molecule comprising at least 15 nucleotides.

Perryman *et al* (U.S. Patent Number 6,323,020) disclose of an isolated nucleic acid molecule comprising a DNA coding sequence for an immunogenic *C. parvum* polypeptide with a molecular weight of 23 kDa. Perryman *et al* further disclose of vectors, host cells, and methods of expressing the polypeptide. (See claims and column 5).

In view that Applicant's specification sets forth that *C. parvum* antigenic polypeptide 2 is determined to be 21.8 kDa, and that the nucleic acid disclosed by Perryman *et al* encodes a *C.*

Art Unit: 1645

parvum polypeptide with a molecular weight of 23 kDa, the disclosure of Perryman *et al* is deemed to anticipate the claimed invention.

For reasons of record in Paper Number 10, as well as the reasons set forth above, this rejection is maintained.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached

Art Unit: 1645

on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

June 3, 2003